Rec'd 11/16/06
Revised

SUMMARY OF SAFETY AND EFFECTIVENESS

Assigned 510(k) Number

The assigned 510(k) number is _____K063045_____.

DEC - 5 2006

Sponsor Name and Address

Diagnostic Products Corporation
Corporate Offices
5210 Pacific Concourse Drive
Los Angeles, CA
90045-6900
(310) 645-8200

Contact

Deborah L. Morris
Director, Clinical Affairs and Regulatory Submissions
(310) 645-8200 extension 7426
dmorris@dpconline.com

Device Name

Trade Name:	IMMULITE® 2000 Vancomycin, IMMULITE 2500 Vancomycin
Classification:	Class II device, LEH 21 CFR 862.3950
DPC Catalog Number:	L2KVN2 (200 tests); L2KVN6 (600 tests), L5KVN2 (200 tests); L5KVN6 (600 tests)

Description of Device

The IMMULITE 2000, IMMULITE 2500 Vancomycin assay is a solid phase competitive chemiluminescent enzyme immunoassay. The solid phase (bead) is coated with ligand-labeled vancomycin. The reagent contains alkaline phosphatase (bovine calf intestine) conjugated to monoclonal murine antivancomycin. Vancomycin in the patient sample competes with the ligand-labeled solid phase for vancomycin binding sites on the monoclonal murine anti-vancomycin enzyme conjugate. The excess sample and reagent are removed by a centrifugal wash. Finally, chemiluminescent substrate is added to the bead and signal is generated in proportion to the bound enzyme. The assay includes an automatic on-board predilution of 1/20 prior to immunoreaction. Immunoreaction incubation time is 30 minutes. The sample volume required is 10 µL for the test and 250 µL dead volume. The sample types are serum and plasma (heparin or EDTA).

Vancomycin Adjustors for the IMMULITE 2000/IMMULITE 2500: Adjustors are used to correlate the signal counts per second (CPS) of the IMMULITE platform instrument in

the user's lab to those of the Master Curve and to account for the changes in reagent enzyme activity and/or operating conditions. The Vancomycin Adjustors, included in the reagent kit, are two levels (Low and High) of lyophilized vancomycin in a human serum/buffer matrix.

Function of Calibrators and Adjustors in the IMMULITE Family of Instruments: In all IMMULITE platform instruments, calibrators are used at the site of manufacture to establish the Master Curve, which is encoded in the kit barcode label. The calibrators are not provided to the customers because the calibration of a specific kit lot is completed at the DPC manufacturing site. Adjustors are used to correlate the signal counts per second (CPS) of the particular IMMULITE instrument in the user's lab to those of the Master Curve and to account for the changes in reagent enzyme activity and/or operating conditions. The quality of the adjustment is monitored by reviewing the slope and the intercept of the adjustment process, not the target values of the adjustors. The acceptance criteria of the slope and the intercept are specified in the Acceptability Criteria section in the specific IMMULITE platform instrument Operator's Manual. Therefore, concentrations of the adjustors are not provided to customers.

Indications for Use

IMMULITE® 2000 Vancomycin assay is intended for use as follows:

> For *in vitro* diagnostic use with the IMMULITE 2000 Analyzer – for the quantitative measurement of vancomycin in serum and plasma (EDTA or heparinized), as an aid in monitoring the therapeutic administration of this antibiotic.

The IMMULITE® 2500 Vancomycin assay is intended for use as follows:

> For *in vitro* diagnostic use with the IMMULITE 2500 Analyzer – for the quantitative measurement of vancomycin in serum and plasma (EDTA or heparinized), as an aid in monitoring the therapeutic administration of this antibiotic.

Manufacturing Site

The IMMULITE 2000, IMMULITE 2500 Vancomycin assay is manufactured by Diagnostic Products Corporation at the following locations:

Diagnostic Products Corporation
Reagent Manufacturing Division
5700 West 96th Street
Los Angeles, CA 90045-5597
FDA Establishment #: 2017183

Diagnostic Products Corporation

Corporate Offices
5210 Pacific Concourse Drive
Los Angeles, CA 90045-6900
FDA Establishment #: 3005250747

Comparison to the Predicate

A summary of the features of the IMMULITE 2000/IMMULITE 2500 Vancomycin ssay and the predicate device (AxSYM® Vancomycin II) (K955851) is presented below.

Item	IMMULITE 2000/2500	AxSYM Vancomycin II
Assay Type	Immunoassay	Immunoassay
Antiserum	Monoclonal (mouse)	Monoclonal (mouse)
Cut-Off	N/A	N/A
Intended Use	For *in vitro* diagnostic use with the IMMULITE 2000 or IMMULITE 2500 Analyzer – for the quantitative measurement of vancomycin in serum and plasma (EDTA or heparinized), as an aid in monitoring the therapeutic administration of this antibiotic.	The AxSYM Vancomycin II assay is a reagent system for the quantitative measurement of vancomycin, an antibiotic drug, in serum or plasma. The measurements obtained are used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to ensure appropriate therapy.
Reportable Range	3.0 µg/mL – 50 µg/mL	3.00 µg/mL – 100 µg/mL
Analytical Sensitivity (limit of blank, detection)	0.4 µg/mL Limit of Blank 0.9 µg/mL Limit of Detection	2.00 µg/mL (analytical sensitivity)
Sample Volume	10 µL IMM 2000 10 µL IMM 2500	Varies depending on the type of sample container. For sample cups, 150 µL (STAT: 94 µL). Minimum volumes calculated by AxSYM System.
Sample Type	Serum and plasma (heparin, EDTA)	Serum and plasma (sodium heparin, citrate, EDTA, oxalate)
Interferences	No significant interference from: Bilirubin up to 200 mg/L Hemoglobin up to 600 mg/dL Triglycerides up to 3000 mg/dL	Less than 10% interference from: Bilirubin up to 20 mg/dL Hemoglobin up to 1.0 g/dL Triglycerides up to 2300 mg/dL Total Protein from 3 - 10 g/dL
Adjustment Interval	2 weeks	Per AxSYM System Operator's Manual

Item	IMMULITE 2000/2500	AxSYM Vancomycin II
Calibration Range (Standardization)	0.0 µg/mL – 100 µg/mL (VANCOMYCIN HYDROCHLORIDE CRS batch 2).	0.00 µg/mL – 100 µg/mL (AxSYM Vancomycin II Standard Calibrators)

Standards/Guidance Documents Referenced

1) Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision Performance of Quantitative Methods; Approved Guideline-Second Edition.* CLSI document EP5-A2 (ISBN 1-56238-000-0). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.
2) Clinical Laboratory Standard Institute (CLSI). *Protocols for the Determination of Limits of Detection and Limits of Quantitation*; Approved Guideline. CLSI document EP17-A Vol 24 No 34. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

Reportable Range

The reportable range for the IMMULITE 2000/IMMULITE 2500 Vancomycin assay 3-50 µg/mL.

Limit of Blank

The determination of Limit of Blank was guided by Clinical Laboratory Standard Institute (CLSI). *Protocols for the Determination of Limits of Detection and Limits of Quantitation*; Approved Guideline. CLSI document EP17-A Vol 24 No 34. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

This guideline defines Limit of Blank (LoB) as the mean or (more conservatively) the highest value expected to be seen in a series of results for samples that contain no analyte.

Sixty replicates of a zero analyte heparin plasma and serum sample as well as the assay zero calibrator were assayed in 3 IMMULITE 2000 kit lots using 3 IMMULITE 2000 instruments per lot and in one IMMULITE 2500 kit lot using 3 instruments per lot in one run per sample type/lot/instrument. IMMULITE 2000/IMMULITE 2500 Vancomycin has a competitive assay format with decreasing chemiluminescent output associated with increasing vancomycin concentration. Limit of Blank (LoB) was computed parametrically as the mean chemiluminescent output measured in counts per second (CPS) minus 1.65 * total SD_{CPS} for each instrument, kit lot, and sample type. The computed LoB_{CPS} were then transformed into vancomycin doses. The aggregate results were assessed for the most conservative package insert claim.

The LoB claim for the IMMULITE 2000 and IMMULITE 2500 is 0.4 µg/mL.

Limit of Detection

The determination of Limit of Detection was guided by Clinical Laboratory Standard Institute (CLSI). *Protocols for the Determination of Limits of Detection and Limits of Quantitation*; Approved Guideline. CLSI document EP17-A Vol 24 No 34. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004. This guideline defines the Limit of Detection (LoD) as the actual concentration at which an observed test result is likely to exceed the Limit of Blank (LoB) and may therefore be declared as detected. The general formula for LoD = LoB + 1.65 * SD.

Five different samples with relevant low concentrations of vancomycin at the range greater than LoB to 4 * LoB (>0.4 µg/mL to 1.6 µg/mL) were assayed using 3 IMMULITE 2000 kit lots on 2 IMMULITE 2000 instruments per lot and using one IMMULITE 2500 kit lot using 2 instruments. Eight runs of 2 replicates per sample were completed on 8 separate days. The sample-specific LoD was calculated as LoB + 1.65 * SD_{sample} for each sample on each instrument used for each kit lot. The aggregate results were assessed for the most conservative package insert claim.

The LoD claim for the IMMULITE 2000 and IMMULITE 2500 is 0.9 µg/mL.

Precision

Precision performance studies were guided by CLSI document EP5-A2 Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision Performance of Quantitative Methods; Approved Guideline-Second Edition.* CLSI document EP5-A2 (ISBN 1-56238-000-0). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

The study was conducted using three different kit lots on the IMMULITE 2000 platform and one lot on the IMMULITE 2500, assaying two aliquots of each test sample in two runs per day over 20 different days (not necessarily consecutive) for a total of 80 replicates per test sample per lot. Two instruments were used per lot.

Precision pools targeted clinically important cut-off values. Since the peak therapeutic range of vancomycin is from 25-40 µg/mL, the therapeutic trough levels range from 5–10 µg/mL, and trough toxicity may be of concern at levels above 10 µg/mL, precision pools targeted 5, 10, 20, 30, and 45 µg/mL.

For the IMMULITE 2000, maximum statistics across 3 lots using 2 instruments per lot indicate that intra- and inter-assay CV% over the range of approximately 5 to 47 µg/mL are not greater than 10.2% and 6.8%, respectively.

For the IMMULITE 2500, maximum statistics for one kit lot using 2 instruments indicate that intra- and inter-assay CV% over the range of approximately 5 to 45 µg/mL are not greater than 6.1% and 6.0%, respectively.

Linearity

Dilutions of 10 patient samples (neat, 4 in 8, 2 in 8 and 1 in 8) across the therapeutic range of the assay (9 to 46 µg/mL) were assayed in the IMMULITE 2000/IMMULITE 2500 Vancomycin assay in triplicate with the mean taken as the final result. Average recovery (% observed/expected) for patient samples tested in the IMMULITE 2000/IMMULITE 2500 Vancomycin assay was 96.0%.

Spiked Recovery

Spiked recovery experiments test the ability of an assay to quantitatively recover added analyte. Average % recovery for 6 patient sample pools spiked with various concentrations of 3 different spiking solutions were tested in the IMMULITE 2000/IMMULITE 2500 Vancomycin assay. The average % recovery for these spiked patient samples was 101%.

Interfering Substances

The IMMULITE 2000/IMMULITE 2500 Vancomycin assay was tested for interference by bilirubin, hemoglobin and triglycerides.

Presence of conjugated or unconjugated bilirubin in concentrations up to 20 mg/dL has no effect on results within the precision of the assay.

Presence of hemoglobin in concentrations up to 600 mg/dL has no effect on results within the precision of the assay.

Presence of triglycerides in concentrations up to 3,000 mg/dL has no effect on results within the precision of the assay.

Cross-Reactivity

Potential serum cross-reactants were spiked at concentrations listed in the following table into a neat normal human serum sample and a human serum sample spiked with 25 µg/mL vancomycin. The IMMULITE 2000/IMMULITE 2500 Vancomycin assay is highly specific for vancomycin. Results are presented below for potential cross-reactants tested in the vancomycin-spiked human serum sample. There was no detectable cross-reactivity to the materials tested.

Potential Cross Reactant	Concentration of potential cross-reactant (µg/mL)	Sample Tested[1]			Cross-Reactivity[2]
		# of Replicates	Obs. Mean Result After Spike	SD (CV%)	
Acetaminophen	500	2	23.47	0.30 (1.3)	ND
Amikacin	500	2	22.89	0.13 (0.6)	ND
Ampicillin	500	2	22.56	0.18 (0.8)	ND
Amphotericin B	500	2	23.85	0.36 (1.5)	ND

[1] 25 µg/mL vancomycin added to human serum sample

[2] ND = Not Detectable

Potential Cross Reactant	Concentration of potential cross-reactant (µg/mL)	Sample Tested[1]			Cross-Reactivity[2]
		# of Replicates	Obs. Mean Result After Spike	SD (CV%)	
Bendroflumethiazide	500	2	22.99	0.31 (1.3)	ND
Caffeine	500	2	22.73	0.41 (1.8)	ND
Carbenicillin	500	2	22.12	1.03 (4.7)	ND
Cefamandole Nafate	500	2	23.91	0.72 (3.0)	ND
Cefazolin	500	2	23.01	0.35 (1.5)	ND
Cephalexin	500	2	23.35	0.20 (0.9)	ND
Cephalosporin C	500	2	22.69	1.27 (5.6)	ND
Cephalothin	500	2	23.49	0.71 (3.0)	ND
Chloramphenicol	500	2	23.13	0.80 (3.5)	ND
Chlorothiazide	500	2	22.28	0.64 (2.9)	ND
Ciprofloxacin	500	2	23.32	0.78 (3.3)	ND
Clindamycin	500	2	22.30	0.34 (1.5)	ND
Crystalline Degradation Product-1 (CDP-1)	10	2	24.36	1.10 (4.5)	ND
Crystalline Degradation Product-1 (CDP-1)	20	2	23.33	0.57 (2.4)	ND
Crystalline Degradation Product-1 (CDP-1)	25	2	24.01	1.03 (4.3)	ND
Crystalline Degradation Product-1 (CDP-1)	50	2	22.96	0.74 (3.2)	ND
Crystalline Degradation Product-1 (CDP-1)	100	2	23.05	0.52 (2.3)	ND
Erythromycin	500	2	23.41	0.82 (3.5)	ND
Ethacrynic Acid	500	2	22.89	0.76 (3.3)	ND
Ethambutol	500	2	23.31	0.83 (3.6)	ND
5-Fluorocytosine	500	2	23.15	0.88 (3.8)	ND
Furosemide	500	2	23.30	0.49 (2.1)	ND
Fusidic Acid	500	2	23.43	0.32 (1.4)	ND
Gentamycin	500	2	23.54	0.36 (1.5)	ND
Sodium heparin	500	2	23.53	0.25 (1.1)	ND
Hydrochlorothiazide	500	2	24.32	1.45 (6.0)	ND
Ibuprofen	500	2	24.17	0.59 (2.4)	ND
Isoniazid	500	2	23.97	0.26 (1.1)	ND
Kanamycin A	500	2	23.70	0.57 (2.4)	ND
Kanamycin B	500	2	22.54	0.33 (1.5)	ND
Lincomycin	500	2	22.15	0.91 (4.1)	ND
Methylprednisolone	500	2	23.60	0.31 (1.3)	ND
Methotrexate	500	2	22.06	0.00 (0.0)	ND
Nalidixic Acid	500	2	23.66	2.02 (8.5)	ND
Naproxen	500	2	22.10	0.25 (1.1)	ND
Neomycin	500	2	22.02	0.13 (0.6)	ND
Netilmicin	500	2	22.75	0.04 (0.2)	ND
Niacin (Nicotinic Acid)	500	2	22.29	0.15 (0.7)	ND
Nitrofurantoin	500	2	22.94	0.57 (2.5)	ND
Oxaprozin	500	2	23.49	0.04 (0.2)	ND
Oxytetracycline	500	2	23.20	0.49 (2.1)	ND
Penicillin G Potassium Salt	500	2	22.51	0.11 (0.5)	ND
Penicillin V Potassium Salt	500	2	22.56	0.65 (2.9)	ND
Phenacetin	500	2	23.00	1.19 (5.2)	ND
Prednisolone	500	2	22.97	1.17 (5.1)	ND
Prednisone	500	2	22.32	0.06 (0.3)	ND

Potential Cross Reactant	Concentration of potential cross-reactant (µg/mL)	Sample Tested[1]			Cross-Reactivity[2]
		# of Replicates	Obs. Mean Result After Spike	SD (CV%)	
Rifampin	500	2	22.92	0.70 (3.1)	ND
Salicylic Acid	500	2	23.90	0.14 (0.6)	ND
Sisomicin	500	2	23.13	0.78 (3.4)	ND
Spectinomycin	500	2	23.52	0.79 (3.4)	ND
Streptomycin	500	2	23.47	0.28 (1.2)	ND
Sulfadiazine	500	2	22.34	0.54 (2.4)	ND
Sulfamethoxazole	500	2	24.11	1.69 (7.0)	ND
Sulfisoxazole	500	2	23.75	0.92 (3.9)	ND
Teicoplanin	10	2	24.80	1.10 (4.4)	ND
Teicoplanin	25	2	23.62	0.74 (3.1)	ND
Teicoplanin	50	2	24.65	1.08 (4.4)	ND
Teicoplanin	100	2	23.41	0.11 (0.5)	ND
Tetracycline	500	2	22.11	0.25 (1.1)	ND
Ticarcillin	500	2	23.93	0.01 (0.0)	ND
Tobramycin	500	2	23.65	0.39 (1.6)	ND
Trimethoprim	500	2	23.18	0.06 (0.3)	ND

[1] 25 µg/mL vancomycin added to human serum sample

[11] ND = Not Detectable

Albumin, cholesterol, IgG, and heparin were spiked at concentrations listed in the following table into a neat normal human serum sample and a human serum sample spiked with 25 µg/mL vancomycin. The IMMULITE 2000/IMMULITE 2500 Vancomycin assay is highly specific for vancomycin. Results are presented below for potential cross-reactants tested in the vancomycin-spiked human serum sample. There was no detectable cross-reactivity to the materials tested.

Potential Cross Reactant	Concentration of potential cross-reactant	Sample Tested[i]			Cross-reactivity[ii]
		# of Replicates	Obs. Mean	SD	
Albumin	10 g/dL	2	23.96	0.53 (2.2)	ND
Cholesterol	500 mg/dL	2	26.06	0.81 (3.1)	ND
IgG	6g/dL	2	24.60	0.47 (1.9)	ND
Heparin	500 USP units/mL	2	23.98	0.58 (2.4)	ND

[i] 25 µg/mL vancomycin added to each human serum sample

[ii] ND = Not Detectable

Human Anti-Mouse Antibodies (HAMA) and rheumatoid factor (RF) were also analyzed for potential interference/cross-reactivity. Six normal human samples were spiked with 6 different concentrations of HAMA. These HAMA-spiked samples were assayed neat and also spiked with 25 µg/mL of vancomycin. Five RF-positive human samples and one normal (no RF) human sample were assayed neat and also spiked with 25 µg/mL of vancomycin.

The IMMULITE 2000/IMMULITE 2500 Vancomycin assay is highly specific for vancomycin. Results are presented below for potential cross-reactants tested in the vancomycin-spiked human serum sample. There was no detectable interference in the samples tested.

Potential Cross-reactant sample	Concentration of potential interferent	Sample Tested[i]			% Cross-reactivity[ii]
		# of Replicates	Obs. Mean	SD (CV%)	
HAMA sample 1	100 ng/mL	2	25.98	0.54 (2.1)	ND
HAMA sample 2	188 ng/mL	2	26.02	1.63 (6.3)	ND
HAMA sample 3	250 ng/mL	2	25.38	1.22 (4.8)	ND
HAMA sample 4	500 ng/mL	2	25.31	1.65 (6.5)	ND
HAMA sample 5	1000 ng/mL	2	25.83	1.71 (6.6)	ND
HAMA sample 6	1880 ng/mL	2	26.11	0.87 (3.3)	ND
RF sample 1	1007 IU/mL	2	24.22	1.34 (5.5)	ND
RF sample 2	1045 IU/mL	2	26.83	0.47 (1.8)	ND
RF sample 3	2330 IU/mL	2	25.41	1.08 (4.3)	ND
RF sample 4	2025 IU/mL	2	26.53	0.91 (3.4)	ND
RF sample 5	833 IU/mL	2	24.49	0.93 (3.8)	ND

[i] 25 µg/mL vancomycin added to each human serum sample

[ii] ND = Not Detectable

Alternate Sample Types

The IMMULITE 2000/IMMULITE 2500 Vancomycin assay is indicated for use in serum and plasma. A sample type correlation study assessed the degree of equivalence between serum and heparinized plasma, EDTA plasma, and SST serum.

Matched sets of human serum, SST, lithium heparin and EDTA samples spiked with various concentrations of vancomycin to obtain values from <3 µg/mL to 50 µg/mL were assayed. Each individual sample was run in duplicate and the mean taken as the final result. Regression analyses are presented below.

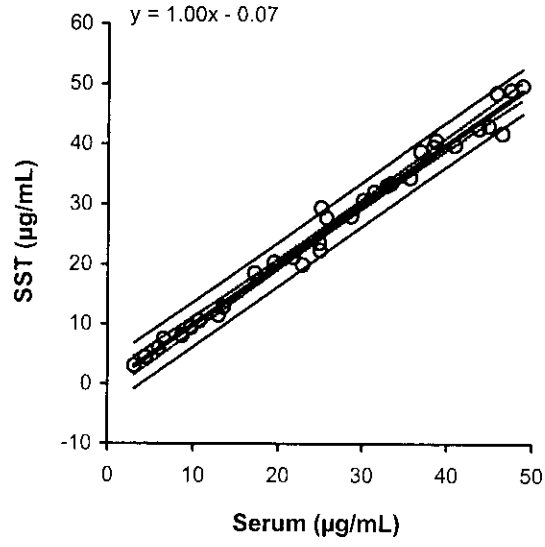
SST Serum Separator Tube (Y) vs Serum (X): N=33

Linear Least Squares Regression (illustrated below): Y= 1.00 X - 0.07; slope = 1.00 (95% CI: 0.96 to 1.05); intercept = -0.07 (95% CI: -1.43 to 1.28); r = 0.99

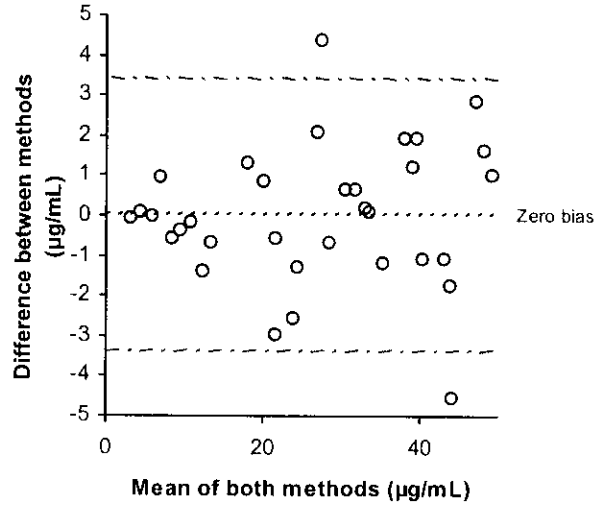
Deming Regression: Y= 1.01 X – 0.28 slope = 1.01 (95% CI: 0.97 to 1.06); intercept = -0.28 (95% CI: -1.64 to 1.09)

Mean serum = 26.7 µg/mL
Mean SST = 26.7 µg/mL

Linear Least Squares Plot



Bland-Altman difference plot *(the differences between the results of two assays are plotted against the averages of the two assays)*



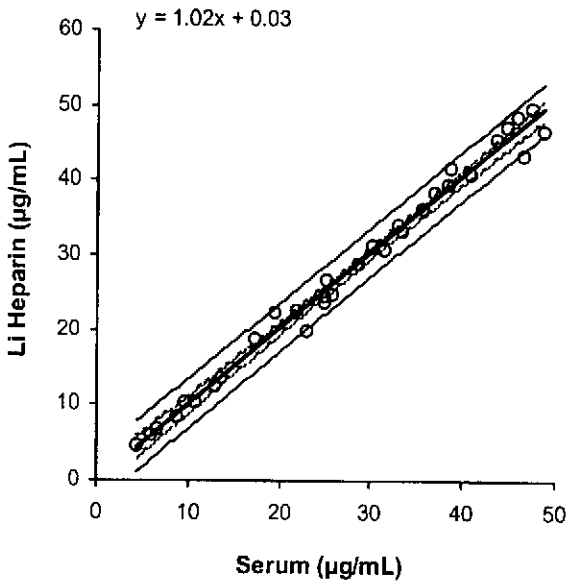
Lithium heparin (Y) vs Serum (X): N=32

Linear Least Squares Regression (illustrated below): Y=1.02 X + 0.03; slope = 1.02 (95% CI: 0.97 to 1.06); intercept = 0.03 (95% CI: -1.25 to 1.30); r = 0.99

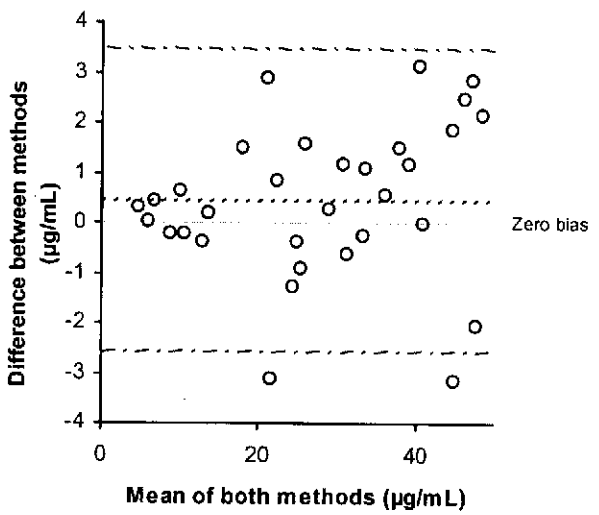
Deming Regression: Y= 1.02 X – 0.15; slope = 1.02 (95% CI: 0.98 to 1.06); intercept = -0.15 (95% CI: -1.43 to 1.14)

Mean serum = 27.5 µg/mL
Mean lithium heparin = 27.9 µg/mL

Linear Least Squares Plot



Bland-Altman difference plot *(the differences between the results of two assays are plotted against the averages of the two assays)*



EDTA (Y) vs Serum (X): N=31

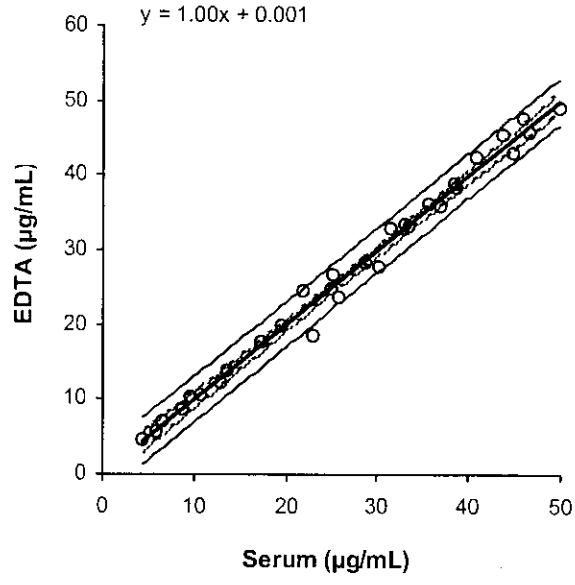
Linear Least Squares Regression (illustrated below): Y= 1.00 X + 0.001; slope = 1.00 (95% CI: 0.96 to 1.04); intercept = 0.001 (95% CI: -1.19 to 1.19); r = 0.99

Deming Regression: Y=1.01 X – 0.15; slope =1.01 (95% CI: 0.97 to 1.05); intercept = -0.15 (95% CI: -1.35 to 1.05)

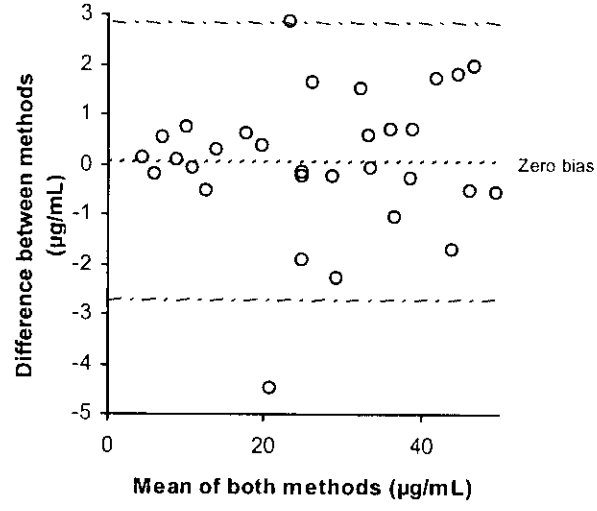
Mean serum = 26.8 µg/mL

Mean EDTA = 26.9 µg/mL

Linear Least Squares Plot



Bland-Altman difference plot *(the differences between the results of two assays are plotted against the averages of the two assays)*



Assay Kit Stability

Kit stability testing was conducted on multiple lots of the IMMULITE 2000/IMMULITE 2500 Vancomycin assay and included the following assessments:

- Real-time stability at long term package insert storage conditions

- Stress (accelerated) conditions to simulate storage/stress conditions that might occur during shipment to and storage at customer facilities. Stress studies also support real-time stability.
  - 3-Day storage at 37°C
  - 7-Day storage at room temperature (15-30 °C)
  - 3 Freeze/thaw cycles (freeze -30°C to -5°C, thaw at 2-8°C)

To date, results of real-time and accelerated stress studies support the claim of 360 days shelf life for the IMMULITE 2000/IMMULITE 2500 Vancomycin assay kits when stored at 2-8°C.

Clinical Sample Population

The following assay methods were compared using endogenous serum from patients being treated with vancomycin. Multiple IMMULITE 2000 and IMMULITE 2500 instruments were used. Results are presented below comparing 162 endogenous serum patient Vancomycin levels in the IMMULITE 2000 versus the predicate AxSYM Vancomycin II and IMMULITE 2500 versus the predicate AxSYM Vancomycin II. Results show high correlation (r=0.97) between both platforms and the AxSYM. Results are also presented below comparing 164 endogenous serum patient Vancomycin levels in the IMMULITE 2500 versus the IMMULITE 2000. Results show high correlation (r=0.970) between methods. High correlation indicates equivalence of assays.

IMMULITE 2000 (Y) vs AxSYM Vancomycin II (X): N=162

Reference Method Sampling Range: 3.70 – 38.6 µg/mL

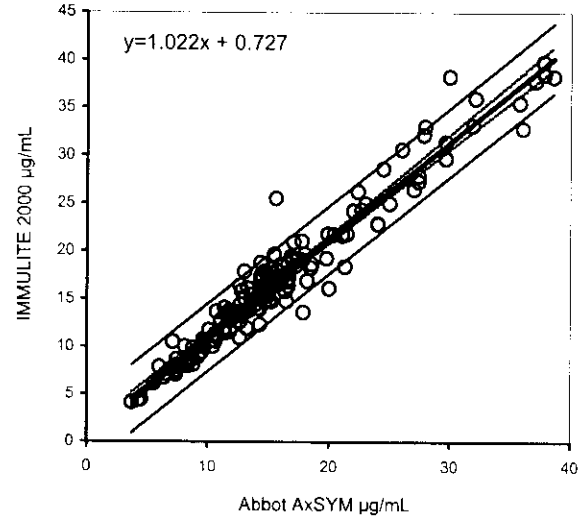
Linear Least Squares Regression (illustrated below): Y=1.022 X + 0.727; slope = 1.022 (95% CI: 0.983 to 1.061); intercept = 0.727 (95% CI: 0.060 to 1.394); r = .971

Deming Regression: Y=1.054X + 0.235; slope = 1.054 (95% CI: 1.013 to 1.094); intercept = 0.235 (95% CI: -0.452 to 0.923)

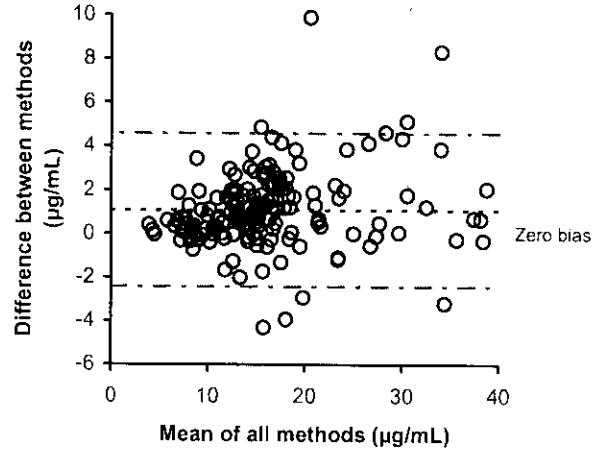
Mean, Median, SD Abbott AxSYM = 15.57 µg/mL, 14.42 µg/mL, 7.14 µg/mL

Mean, Median, SD IMMULITE 2000 = 16.63 µg/mL, 15.58 µg/mL, 7.51 µg/mL

Linear Least Squares Plot:



Bland-Altman difference plot (the differences between the results of two assays are plotted against the averages of the two assays)



IMMULITE 2500 Lot 111A (Y) vs AxSYM Vancomycin II (X): N=162

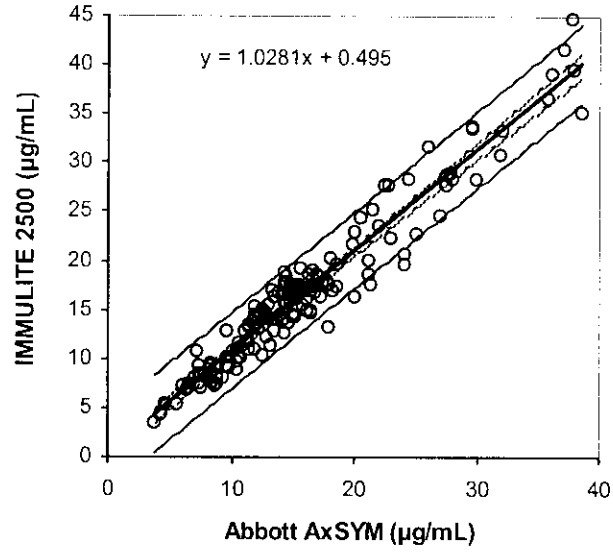
Reference Method Sampling Range: 3.70 – 38.6 µg/mL

Linear Least Squares Regression (illustrated below): Y=1.028 X + 0.495; slope = 1.028 (95% CI: 0.985 to 1.071); intercept = 0.495 (95% CI: -0.236 to 1.226); r = 0.966

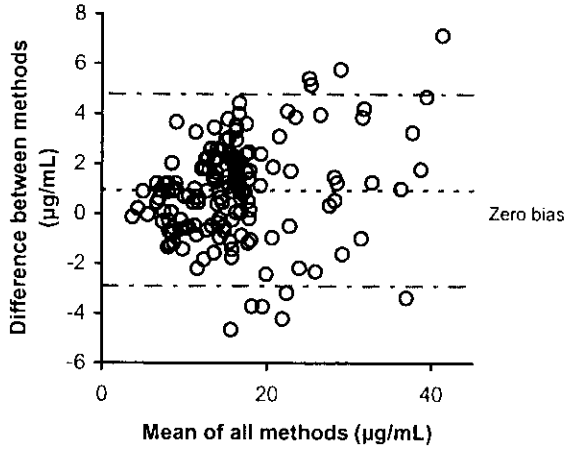
Deming Regression: Y=1.066X – 0.097; slope = 1.066 (95% CI: 1.022 to 1.110); intercept = -0.097 (95% CI: -0.854 to 0.661)
Mean, Median, SD Abbott AxSYM = 15.57 µg/mL, 14.42 µg/mL, 7.14 µg/mL

Mean, Median, SD IMMULITE 2500 Lot 111A = 16.50 µg/mL, 15.64 µg/mL, 7.60 µg/mL

Linear Least Squares Plot



Bland-Altman difference plot (the differences between the results of two assays are plotted against the averages of the two assays)



IMMULITE 2500 (Y) vs IMMULITE 2000 (X): N=164

Reference Method Sampling Range: 4.11 – 39.8 µg/mL

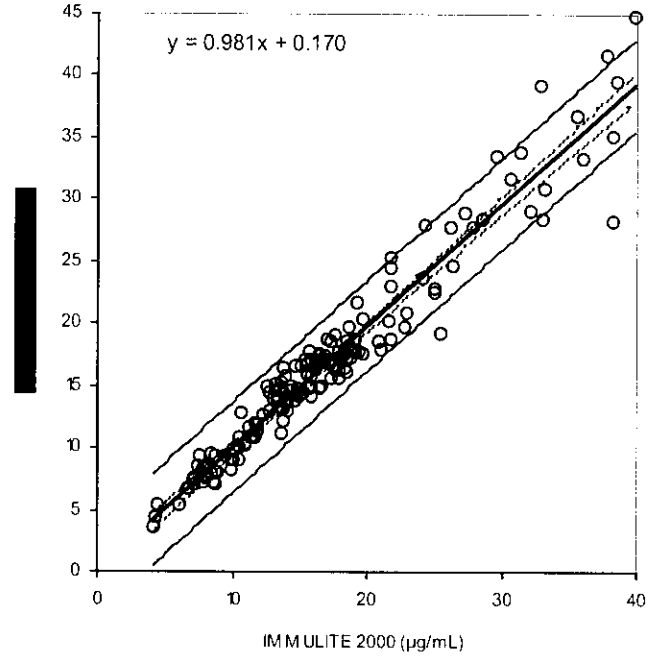
Linear Least Squares Regression (illustrated below): Y=0.981X + 0.170; slope = 0.981 (95% CI: 0.943 to 1.019); intercept = 0.170 (95% CI: -0.526 to 0.866); r = 0.970

Deming Regression: Y=1.011X – 0.342; slope =1.011 (95% CI: 0.972 to 1.051); intercept =-0.342 (95% CI: -1.060 to 0.376)

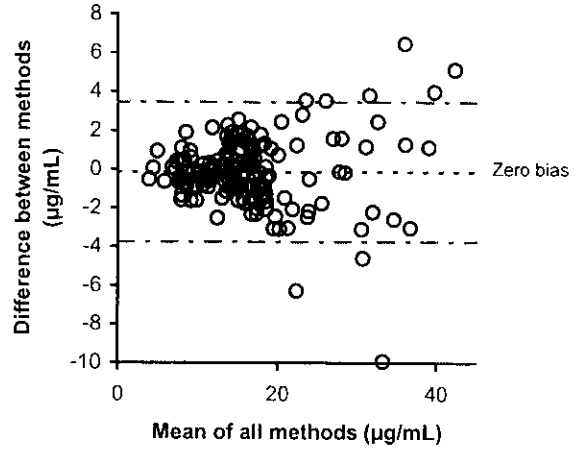
Mean, Median, SD IMMULITE 2000 = 16.65 µg/mL, 15.66 µg/mL, 7.47 µg/mL

Mean, Median, SD IMMULITE 2500 = 16.50 µg/mL, 15.73 µg/mL, 7.55 µg/mL

Linear Least Squares Plot:



Bland-Altman difference plot (the differences between the results of two assays are plotted against the averages of the two assays)



Conclusions

The IMMULITE 2000/IMMULITE 2500 Vancomycin assay demonstrates acceptable analytical performance including analytical sensitivity and specificity, precision, linearity, and method comparison to the FDA cleared predicate device, Abbott AxSYM Vancomycin II.

The IMMULITE 2000/IMMULITE 2500 Vancomycin assay is therefore substantially equivalent to the FDA cleared predicate Abbott AxSYM Vancomycin II and thereby safe and effective for the following intended use:

IMMULITE® 2000 Vancomycin assay is intended for use as follows:

> For in vitro diagnostic use with the IMMULITE 2000 Analyzer – for the quantitative measurement of vancomycin in serum and plasma (EDTA or heparinized), as an aid in monitoring the therapeutic administration of this antibiotic.

The IMMULITE® 2500 Vancomycin assay is intended for use as follows:

> For in vitro diagnostic use with the IMMULITE 2500 Analyzer – for the quantitative measurement of vancomycin in serum and plasma (EDTA or heparinized), as an aid in monitoring the therapeutic administration of this antibiotic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Deborah Morris
Diagnostic Products Corp.
5210 Pacific Concource Dr.
Los Angeles, CA 90045-6900

DEC - 5 2006

Re: k063045
Trade/Device Name: Immulite 2000 Vancomycin and Immulite 2500 Vancomycin
Regulation Number: 21 CFR 862.3950
Regulation Name: Vancomycin test system
Regulatory Class: Class II
Product Code: LEH
Dated: October 2, 2006
Received: October 4, 2006

Dear Ms. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

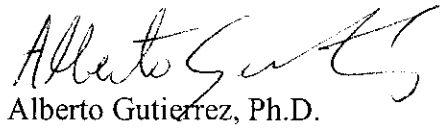
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063045

Device Name: IMMULITE® 2000 Vancomycin
IMMULITE® 2500 Vancomycin

Indications For Use:

IMMULITE® 2000 Vancomycin assay is intended for use as follows:

For in vitro diagnostic use with the IMMULITE 2000 Analyzer – for the quantitative measurement of vancomycin in serum and plasma (EDTA or heparinized), as an aid in monitoring the therapeutic administration of this antibiotic.

The IMMULITE® 2500 Vancomycin assay is intended for use as follows:

For in vitro diagnostic use with the IMMULITE 2500 Analyzer– for the quantitative measurement of vancomycin in serum and plasma (EDTA or heparinized), as an aid in monitoring the therapeutic administration of this antibiotic.

Prescription Use **X** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K063045